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Message Text

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PAGE 01 STATE 065948

15
ORIGIN HEW-08

INFO OCT-01 EUR-25 ISO-00 SCI-06 COME-00 RSC-01 /041 R

66612
DRAFTED BY:DHEW/FDA:LRSHELTON
3/28/74 EXT 34480
APPROVED BY:SCI:MSBEAUBIEN
DHEW/OIH:MACODDING EUR/NE:CFLOYD (INFO)
---------- 055139
R 022024Z APR 74
FM SECSTATE WASHDC
TO AMEMBASSY LONDON

UNCLAS STATE 065948

FOR E/GEP

E.O. 11652: N/A
TAGS: TBIO, UK
SUBJECT: RECALL OF DESERET INTRAVENOUS CATHETERS

REF: LONDON 03303; STATE 037128

1. FDA SUGGESTS THAT FOLLOWING MAY BE HELPFUL TO DHSS:
TWO LOTS OF CATHETERS MANUFACTURED BY DESERET WERE FOUND BY FDA
TO BE CONTAMINATED WITH YEAST AND GRAM POSITIVE RODS AND COCCI.

FURTHER INVESTIGATIONS BY FIRM'S CONSULTANTS SHOWED LOW-LEVEL
CONTAMINATION IN 12 ADEITIONAL LOTS OF A VARIETY OF CATHETERS.

A REVIEW OF THE FIRM'S STERILIZATION EQUIPMENT (ETO) REVEALED
SERIOUS DESIGN DEFICIENCIES IN THE SMALLER OF THEIR TWO
STERILIZERS AND DEFICIENCIES IN THEIR IN-HOUSE STERILITY TESTING
PROCEDURES. RUSH

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Message Attributes

Automatic Decaptioning: X
Capture Date: 01 JAN 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: CONSUMER PROTECTION, MEDICAL CARE, FOOD & DRUG REGULATIONS, MEDICAL FACILITIES
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Draft Date: 02 APR 1974
Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Authority: n/a
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 JAN 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
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Type: TE
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